IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC.-FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC., ANDRX EU LTD., AND ANDRX LABS, L.L.C., Plaintiffs, v. LUPIN LTD., and LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 09-037 (RBK)(JS) CONSOLIDATED **JURY TRIAL DEMANDED**
SHIONOGI, INC., ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC.-FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC., ANDRX EU LTD., AND ANDRX LABS, L.L.C., Plaintiffs, v. MYLAN, INC., and MYLAN PHARMACEUTICALS INC., Defendants.	C.A. No. 10-135 (RBK)(JS)

THE LUPIN DEFENDANTS' ANSWER AND COUNTERCLAIMS
TO THE AMENDED AND SUPPLEMENTAL COMPLAINT

Defendants Lupin Pharmaceuticals, Inc. ("Lupin Pharma") and Lupin Limited ("Lupin Ltd.") (collectively the "Lupin Defendants"), by and through their attorneys, respond to each of the numbered paragraphs to the Amended and Supplemental Complaint for Patent Infringement (the "Complaint") filed against them by Plaintiffs Sciele Pharma, Inc. (n/k/a

Shionogi Pharma Inc.), Andrx Corporation, Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc.-Florida), Andrx Pharmaceuticals, L.L.C., Andrx Labs, L.L.C., Andrx Laboratories (NJ), Inc., and Andrx EU Ltd. ("Plaintiffs") as follows:

The Lupin Defendants deny any and all allegations contained in headings and unnumbered Paragraphs in the Complaint.

1. Upon information and belief, the Lupin Defendants admit the allegations set forth in paragraph 1 of the Complaint.

2. Upon information and belief, the Lupin Defendants admit the allegations set forth in paragraph 2 of the Complaint.

3. The Lupin Defendants admit the first sentence of paragraph 3 of the Complaint. Lupin Pharma further admits that it distributes generic drugs for sale and use throughout the United States, including in this judicial district. Lupin Pharma further admits that it distributes pharmaceutical products, including generic pharmaceutical products, manufactured by Lupin Ltd. The Lupin Defendants deny the remaining allegations made in paragraph 3 of the Complaint.

4. The Lupin Defendants admit: that Lupin Ltd. is a corporation organized and existing under the laws of India, with a place of business at Laxmi Towers, B Wing, Bandra Kuria Complex, Bandra (East), Mumbai, Maharashtra 400 051, India, and with its only places of business located in India; that Lupin Ltd. develops, manufactures, markets and sells pharmaceutical products, including generic pharmaceutical products; and that Lupin Pharma distributes pharmaceutical products, including generic pharmaceutical products manufactured by Lupin Ltd. that have been authorized by the United States Food and Drug Administration under applicable law. The Lupin Defendants deny the remaining allegations made in paragraph 4 of the Complaint.

5. The Lupin Defendants admit: that Lupin Ltd. develops, manufactures, markets and sells pharmaceutical products, including generic pharmaceutical products; that Lupin Pharma distributes pharmaceutical products in the United States, including generic pharmaceutical products manufactured by Lupin Ltd. that have been authorized by the United States Food and Drug Administration under applicable law.. The Lupin Defendants deny the remaining allegations made in paragraph 5 of the Complaint.

6. The Lupin Defendants admit that this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§1331 and 1338(a). Lupin Ltd. denies that venue is proper as to it in this District, but does not contest venue in this District solely for the purposes of this action. Lupin Pharma admits that venue is proper as to it in this District.

7. Lupin Ltd. denies that personal jurisdiction in this District exists as to it in this action. However, the Lupin Defendants do not contest personal jurisdiction in this District, solely for the purposes of this action. The Lupin Defendants deny the remaining allegations made in paragraph 7 of the Complaint.

8. The Lupin Defendants admit that included in ANDA No. 90-692 is a letter from Lupin Ltd. that identifies an employee of Lupin Pharmaceuticals, Inc., as "the United States Agent of Lupin Limited for [this] ANDA." The Lupin Defendants admit that Lupin Pharma participated in the filing of ANDA No. 90-692. The Lupin Defendants deny the remaining allegations made in paragraph 8 of the Complaint.

9. The Lupin Defendants admit: that Lupin Ltd. develops, manufactures, markets and sells pharmaceutical products, including generic pharmaceutical products; that Lupin Pharma distributes pharmaceutical products in the United States, including generic pharmaceutical products manufactured by Lupin Ltd. that have been authorized by the United States Food and Drug Administration under applicable law; that Lupin Ltd. maintains a website

at www.lupinworld.com; and that Lupin Pharma has its offices at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. The Lupin Defendants deny the remaining allegations made in paragraph 9 of the Complaint.

10. The Lupin Defendants deny the allegations made in paragraph 10 of the Complaint.

11. The Lupin Defendants admit that Lupin Pharma has a distribution network in the United States and that Lupin Pharma has formed marketing alliances with other companies in the United States. The Lupin Defendants deny the remaining allegations made in paragraph 11 of the Complaint.

12. The Lupin Defendants admit that Lupin Pharma's website reflects that Amerisource Bergen, Cardinal Health and Walgreens, as well as others, are authorized distributors of record. http://www.lupinpharmaceuticals.com/adrsub.htm#product_a. The Lupin Defendants deny the remaining allegations made in paragraph 12 of the Complaint.

13. The Lupin Defendants admit that the website for Lupin Pharma reflects that Happy Harry's, at 326 Ruthar Drive, in Newark, Delaware, is an authorized distributor for Lupin Pharma, and that the page of Lupin Pharma's website that contains this information bears a copyright date of 2006. http://www.lupinpharmaceuticals.com/ adrsub.htm#product_h The Lupin Defendants admit that, according to a Walgreen's website, Happy Harry's is a Walgreen's Pharmacy, and that the website claims that, before 1987, Happy Harry's was "Delaware's largest drug store chain." http://www.walgreens.com/about/company history/happy.jsp. The Lupin Defendants deny the remaining allegations made in paragraph 13 of the Complaint.

14. The Lupin Defendants admit: that Lupin Ltd. manufactures Suprax®, that Lupin Pharma distributes Suprax® in the United States; and that Suprax® is sold in the United States. The Lupin Defendants admit that the Suprax® package insert states that Suprax® is

"Manufactured for:" Lupin Pharmaceuticals, Inc. The Lupin Defendants deny the remaining allegations made in paragraph 14 of the Complaint.

15. The Lupin Defendants admit that Lupin Pharma has entered into a multi-year agreement for the AeroChamber Plus® line of products with Forest Laboratories, Inc. ("Forest Labs"), and that Lupin Pharma has agreed to use its 50 person sales force to promote this Forest Labs product to pediatricians in the United States. Upon information and belief, the Lupin Defendants admit that Forest Labs' AeroChamber Plus® line of products is distributed throughout the United States. The Lupin Defendants deny the remaining allegations made in paragraph 15 of the Complaint.

16. Lupin Pharma admits that this court has personal jurisdiction over it. The Lupin Defendants deny the remaining allegations made in paragraph 16 of this Complaint.

17. Lupin Ltd. denies that personal jurisdiction exists and denies that venue is proper as to it for this case in this District, but does not contest personal jurisdiction or venue in this District solely for the purposes of this action. The Lupin Defendants deny the remaining allegations made in paragraph 17 of the Complaint.

18. The Lupin Defendants admit: that United States Patent No. 6,099,859 (the "'859 patent"), titled "Controlled Release Oral Tablet Having A Unitary Core," was issued by the United States Patent and Trademark Office ("PTO"); that the issue date set forth on the face of the '859 patent is August 8, 2000; that the assignee on the face of the '859 patent is Andrx Pharmaceuticals, Inc.; and that the Complaint purports to attach a copy of the '859 patent, as Exhibit A. The Lupin Defendants deny that the '859 patent was "duly and legally" issued by the PTO. The Lupin Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations made in paragraph 18 of the Complaint, and, therefore, deny them.

19. The Lupin Defendants admit: that United States Patent No. 6,866,866 (the "'866 patent"), titled "Controlled Release Metformin Compositions," was printed by the United States Patent and Trademark Office ("PTO"); that the issue date set forth on the face of the '866 patent is March 15, 2005; that the assignee on the face of the '866 patent is Andrx Labs, LLC; and that the Complaint purports to attach a copy of the '866 patent, as Exhibit B. The Lupin Defendants deny that the '866 patent was "duly and legally" issued by the PTO. The Lupin Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations made in paragraph 19 of the Complaint, and, therefore, deny them.

20. Upon information and belief, the Lupin Defendants admit that Andrx Labs, LLC is listed by the FDA as the holder of New Drug Application ("NDA") No. 21-574 for Fortamet® brand metformin hydrochloride extended release tablets. Upon information and belief, the Lupin Defendants aver that the '859 and '866 patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for Fortamet®, together with United States Patents No. 6,495,162 and 6,790,459. Upon information and belief, Shionogi markets tablets in the United States under the tradename Fortamet®. The Lupin Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations made in paragraph 20 of the Complaint, and, therefore, deny them.

21. The Lupin Defendants admit that ANDA No. 90-692 was submitted by Lupin Ltd. to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), and that ANDA No. 90-692 seeks FDA approval for the commercial manufacture, use and sale of generic extended release tablet products containing 500 milligrams and 1000 milligrams of metformin hydrochloride ("the ANDA Products"). The Lupin Defendants admit that ANDA No. 90-692 seeks to market the ANDA Products prior to the expiration of the '859 and '866 patents, and that the ANDA contained a certification with respect to those patents, and

with respect to United States Patents No. 6,495,162 and 6,790,459. The Lupin Defendants deny the remaining allegations made in paragraph 21 of the Complaint.

22. The Lupin Defendants admit that on or about December 3, 2008, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Lupin Ltd. sent a statement pursuant to § 505(j)(2)(A)(vii)(IV) statement to Watson Pharmaceuticals and Andrx, in which Lupin Ltd. represented that it had filed ANDA No. 90-692, seeking to market the ANDA Products prior to the expiration of the '859 and '866 patents, and that its ANDA contained a certification with respect to those patents, and with respect to United States Patents No. 6,495,162 and 6,790,459. The Lupin Defendants deny that the remaining allegations set forth in paragraph 22 of the Complaint.

23. The Lupin Defendants admit the allegation in paragraph 23 of the Complaint.

24. The Lupin Defendants admit that Lupin Pharma first sold the ANDA products, which were manufactured by Lupin Ltd., in the United States on September 30, 2011, but otherwise deny the allegations in paragraph 24 of the Complaint.

25. The Lupin Defendants admit that Lupin Pharma first sold the ANDA products, which were manufactured by Lupin Ltd., in the United States on September 30, 2011, but otherwise denies the allegations in paragraph 25 of the Complaint.

26. Upon information and belief, the Lupin Defendants admit the allegations in paragraph 26 of the Complaint.

27. The Lupin Defendants admit that the Court granted Shionogi's motion for preliminary injunction on December 6, 2011, and aver that the Federal Circuit vacated and remanded that order on February 6, 2011, but otherwise denies the allegations in paragraph 27 of the Complaint.

28. The Lupin Defendants admit that they have not recalled the ANDA products, and states that they were not required to recall the ANDA products because the Court specifically denied the portion of Shionogi's motion requesting a recall.

29. The Lupin Defendants admit that the ANDA products continue to be available in the marketplace as of February 13, 2012.

FIRST COUNT (U.S. PATENT NO. 6,099,859)

30. The Lupin Defendants incorporate herein their answers to the allegations made in paragraphs 1 through 29 of the Complaint, as if those answers had been realleged and set forth again in full.

31. The Lupin Defendants deny the allegations made in paragraph 31 of the Complaint.

32. The Lupin Defendants deny the allegations made in paragraph 32 of the Complaint.

33. The Lupin Defendants deny the allegations made in paragraph 33 of the Complaint.

34. Lupin Ltd. and Lupin Pharma admit that they were aware of the '859 patent. The Lupin Defendants deny the remaining allegations made in paragraph 34 of the Complaint.

35. The Lupin Defendants deny the allegations made in paragraph 35 of the Complaint.

SECOND COUNT (U.S. PATENT NO. 6,866,866)

36. The Lupin Defendants incorporate herein their answers to the allegations made in paragraphs 1 through 35 of the Complaint, as if those answers had been realleged and set forth again in full.

37. The Lupin Defendants deny the allegations made in paragraph 37 of the Complaint.

38. The Lupin Defendants deny the allegations made in paragraph 38 of the Complaint.

39. The Lupin Defendants deny the allegations made in paragraph 39 of the Complaint.

40. The Lupin Defendants admit that they were aware of the '866 patent. The Lupin Defendants deny the remaining allegations made in paragraph 40 of the Complaint.

41. The Lupin Defendants deny the allegations made in paragraph 41 of the Complaint.

THIRD COUNT (U.S. PATENT NO. 6,099,859)

42. The Lupin Defendants incorporate herein their answers to the allegations made in paragraphs 1 through 41 of the Complaint, as if those answers had been realleged and set forth again in full.

43. The Lupin Defendants admit: that ANDA No. 90-692 was submitted by Lupin Ltd. to the FDA; that Lupin Pharma is the United States Agent of Lupin Limited for ANDA No. 90-692 to the FDA; and that, at that time, they were aware of the '859 patent. The Lupin Defendants deny the remaining allegations made in paragraph 43 of the Complaint.

44. The Lupin Defendants deny the allegations made in paragraph 44 of the Complaint.

45. The Lupin Defendants deny the allegations made in paragraph 45 of the Complaint.

46. The Lupin Defendants deny the allegations made in paragraph 46 of the Complaint.

47. The Lupin Defendants deny the allegations made in paragraph 47 of the Complaint.

48. The Lupin Defendants deny the allegations made in paragraph 48 of the Complaint.

49. The Lupin Defendants deny the allegations made in paragraph 49 of the Complaint.

50. The Lupin Defendants deny the allegations made in paragraph 50 of the Complaint.

FOURTH COUNT (U.S. PATENT NO. 6,866,866)

51. The Lupin Defendants incorporate herein their answers to the allegations made in paragraphs 1 through 50 of the Complaint, as if those answers had been realleged and set forth again in full.

52. The Lupin Defendants admit: that ANDA No. 90-692 was submitted by Lupin Ltd. to the FDA; that Lupin Pharma is the United States Agent of Lupin Limited for ANDA No. 90-692 to the FDA; and that, at that time, they were aware of the '866 patent. The Lupin Defendants deny the remaining allegations made in paragraph 52 of the Complaint.

53. The Lupin Defendants deny the allegations made in paragraph 53 of the Complaint.

54. The Lupin Defendants deny the allegations made in paragraph 54 of the Complaint.

55. The Lupin Defendants deny the allegations made in paragraph 55 of the Complaint.

56. The Lupin Defendants deny the allegations made in paragraph 56 of the Complaint.

57. The Lupin Defendants deny the allegations made in paragraph 57 of the Complaint.

58. The Lupin Defendants deny the allegations made in paragraph 58 of the Complaint.

59. The Lupin Defendants deny the allegations made in paragraph 59 of the Complaint.

60. The Lupin Defendants deny that the Plaintiffs are entitled to the judgment and relief prayed for in paragraph 60 of the Complaint.

61. The Lupin Defendants further answer that any allegations in the Complaint requiring a response from either or both of them not specifically admitted or denied are denied.

DEFENSES

Further responding to the Complaint, and as additional defenses thereto, the Lupin Defendants assert the following affirmative defenses, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on the Plaintiffs.

FIRST DEFENSE
(Non-infringement of the '859 Patent)

62. The manufacture, use, offer for sale, sale, or importation of the ANDA Products does not and will not infringe any claim of the '859 patent, either literally or under the doctrine of equivalents.

SECOND DEFENSE
(Invalidity of the '866 Patent)

63. One or more of the claims of the '866 patent, if construed to encompass the ANDA Products, are invalid for failing to meet a condition for patentability set forth in 35

U.S.C. § 101 *et seq*. By way of example and not of limitation, one or more of the claims of the '866 patent are invalid under 35 U.S.C. §§ 103 and 112.

THIRD DEFENSE

(Non-infringement of the '866 Patent)

64. The manufacture, use, offer for sale, sale, or importation of the ANDA Products does not and will not infringe any claim of the '866 patent, either literally or under the doctrine of equivalents.

FOURTH DEFENSE
(Invalidity of the '859 Patent)

65. One or more of the claims of the '859 patent, if construed to encompass the ANDA Products, are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 et seq. By way of example and not of limitation, one or more of the claims of the '859 patent are invalid under 35 U.S.C. §§ 103 and 112.

FIFTH DEFENSE
(Failure to State a Claim)

66. To the extent that Plaintiffs allege that submission of ANDA 90-692 makes this case exceptional under 35 U.S.C. § 285, the Complaint fails to state a claim upon which relief can be granted and must be dismissed.

COUNTERCLAIMS

Further responding to the Complaint, the Lupin Defendants allege the following counterclaims, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on the Plaintiffs.

THE PARTIES

67. Lupin Ltd. is an Indian corporation having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

68. Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a Virginia corporation having a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin Ltd. and Lupin Pharma are sometimes referred to herein collectively as "the Lupin Counter-Plaintiffs".

69. Upon information and belief, Sciele Pharma, Inc. ("Sciele") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Five Concourse Parkway, Suite 1800, Atlanta, Georgia 30328.

70. Upon information and belief, Andrx Corporation ("Andrx Corp.") is a Delaware corporation and subsidiary of Watson Pharmaceuticals, Inc., having a place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Andrx Pharmaceuticals, Inc. ("Andrx Pharmaceuticals") is a Florida corporation and subsidiary of Andrx Corp., now known as Watson Laboratories, Inc., having a place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Andrx Pharmaceuticals, L.L.C. and Andrx Labs, L.L.C. are Delaware limited liability companies and subsidiaries of Andrx Corp., having a place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Andrx Laboratories (NJ), Inc. is a Delaware corporation and a subsidiary

of Andrx Corp., having a place of business at 8151 Peters Road, 4th Floor, Plantation, Florida 33324. Upon information and belief, Andrx EU Limited is a UK corporation and subsidiary of Andrx Corp., having a place of business at 8151 Peters Road, 4th Floor, Plantation, Florida 33324. The Andrx companies are hereinafter referred to collectively as "Andrx."

71. Upon information and belief, based upon Plaintiffs' assertion in their Complaint and Plaintiffs' Answer to Counterclaims of Lupin Ltd. and Lupin Pharmaceuticals, Inc., Andrx is the owner of United States Patent No. 6,099,859 ("the '859 patent") titled "Controlled Release Oral Tablet Having A Unitary Core."

72. Upon information and belief, based upon Plaintiffs' assertion in their Complaint and Plaintiffs' Answer to Counterclaims of Lupin Ltd. and Lupin Pharmaceuticals, Inc., Andrx is the owner of United States Patent No. 6,866,866 ("the '866 patent") titled "Controlled Release Metformin Compositions."

73. Upon information and belief, based upon Plaintiffs' assertion in their Complaint and Plaintiffs' Answer to Counterclaims of Lupin Ltd. and Lupin Pharmaceuticals, Inc., Andrx is the owner of United States Patent No. 6,495,162 ("the '162 patent") titled "Controlled Release Oral Tablet Having A Unitary Core." (Attached hereto as Exhibit 1.)

74. Upon information and belief, based upon Plaintiffs' assertion in their Complaint and Plaintiffs' Answer to Counterclaims of Lupin Ltd. and Lupin Pharmaceuticals, Inc., Andrx is the owner of United States Patent No. 6,790,459 ("the '459 patent") titled "Methods for Treating Diabetes Via Administration of Controlled Release Metformin." (Attached hereto as Exhibit 2.)

JURISDICTION AND VENUE

75. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and pursuant to 35 U.S.C. § 271(e)(5), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 et seq.

76. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and under 21 U.S.C. § 355(j)(c), because this is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the '859, '866, '459 and '162 patents are not infringed, and that the '459 and '866 patents are invalid, and because the Plaintiffs and Counter-Defendants have not brought an action alleging infringement of the '459 or '162 patents within 45 days after receiving notice by the Lupin Counter-Plaintiffs pursuant to 21 U.S.C. § 355 (j)(2)(B).

77. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391.

THE CONTROVERSY

78. The Lupin Ltd. holds Abbreviated New Drug Application ("ANDA") No. 90-692 for extended release tablet products containing 500 milligrams and 1000 milligrams of metformin hydrochloride (the "ANDA Products").

79. On or about January 15, 2008, Plaintiffs filed the present action against the Lupin Counter-Plaintiffs alleging infringement of the '859 and '866 patents arising from Lupin Ltd.'s submission of ANDA No. 90-692.

80. Andrx Labs, LLC is listed by the FDA as the holder of New Drug Application ("NDA") No. 21-487 for Fortamet® brand metformin hydrochloride extended release tablets. The '459 and '162 patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for Fortamet®, together with the '859 and '866 patents.

81. The Complaint filed by the Plaintiffs does not assert that either Lupin Ltd. or Lupin Pharma has infringed or will infringe any claim of the '162 or '459 patents. There is a substantial controversy between the parties, by reason of the commencement by the Plaintiffs of actions against the Lupin Counter-Plaintiffs alleging that they infringe the '859 and '866 patents; the listing of the '162 and '459 patents in the Orange Book; and the filing by Lupin Ltd. of ANDA 90-0692 with a certification that all of the Orange Book listed patents relating to the Fortamet® brand metformin product, including the '162 and '459 patents, are invalid and/or will not be infringed by the manufacturer, sale and use of the ANDA Products. The Lupin Counter-Plaintiffs and the Plaintiffs and Counter-Defendants have adverse legal interests with respect to all of the Orange Book listed patents of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The dispute between the Lupin Counter-Plaintiffs and the Plaintiffs and Counter-Defendants with respect to the four Orange Book listed patents is definite, concrete, real and substantial. The dispute touches the legal relations of the parties to this action and admits of specific relief through a decree of conclusive character, establishing whether the four Orange Book listed patents have been or will be infringed by manufacture, sale and use of the ANDA products, and whether the four Orange Book listed patents are valid. The Lupin Counter-Plaintiffs have reason to believe that the Plaintiffs will sue the Lupin Counter-Plaintiffs for infringement of the '162 and '459 patents, as the Plaintiffs have already sued the Lupin Counter-Plaintiffs in this case for alleged infringement of the '866 and '859 patents because they allegedly "manufactured, used, offered to sell, sold, or imported its generic version of FORTAMET" prior to the expiration of those patents. (*See*, *e.g.*, Plaintiffs' Complaint at ¶¶ 45 and 54.)

COUNTERCLAIM COUNT I
(Declaratory Judgment Of Non-infringement of the '859 Patent)

82. The Lupin Counter-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of their Counterclaims.

83. The Lupin Counter-Plaintiffs' commercial manufacture, use, offer for sale, sale, or importation of the ANDA Products have not and will not infringe any claim of the '859 patent.

84. Because the Lupin Counter-Plaintiffs have not infringed and will not infringe any claim of the '859 patent, Plaintiffs are entitled to no damages or other relief from or against either Lupin Ltd. or Lupin Pharma.

COUNTERCLAIM COUNT II
(Declaratory Judgment Of Non-infringement of the '866 Patent)

85. The Lupin Counter-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of their Counterclaims.

86. The Lupin Counter-Plaintiffs' commercial manufacture, use, offer for sale, sale, or importation of the ANDA Products have not and will not infringe any claim of the '866 patent.

87. Because the Lupin Counter-Plaintiffs have not infringed and will not infringe any claim of the '866 patent, Plaintiffs are entitled to no damages or other relief from or against either Lupin Ltd. or Lupin Pharma.

COUNTERCLAIM COUNT III
(Declaratory Judgment Of Non-infringement of the '162 Patent)

88. The Lupin Counter-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of its Counterclaims.

89. The Lupin Counter-Plaintiffs' commercial manufacture, use, offer for sale, sale, or importation of the ANDA Products do not infringe any claim of the '162 patent.

COUNTERCLAIM COUNT IV

(Declaratory Judgment Of Non-infringement of the '459 Patent)

90. The Lupin Counter-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of their Counterclaims.

91. The Lupin Counter-Plaintiffs's commercial manufacture, use, offer for sale, sale, or importation of the ANDA Products do not infringe any claim of the '459 patent.

COUNTERCLAIM COUNT V
(Declaratory Judgment Of Invalidity of the '866 Patent)

92. The Lupin Counter-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of their Counterclaims.

93. One or more of the claims of the '866 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq*. By way of example and not of limitation, one or more of the claims of the '866 patent are invalid under 35 U.S.C. §§ 103 and 112.

COUNTERCLAIM COUNT VI
(Declaratory Judgment Of Invalidity — '459 Patent)

94. The Lupin Counter-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of their Counterclaims.

95. One or more of the claims of the '459 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq*. By way of example and not of limitation, one or more of the claims of the '459 patent are invalid under 35 U.S.C. §§ 103 and 112.

COUNTERCLAIM COUNT VII

(Declaratory Judgment Of Invalidity — '859 Patent)

96. The Lupin Counter-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of their Counterclaims.

97. One or more of the claims of the '859 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq*. By way of example and not of limitation, one or more of the claims of the '859 patent are invalid under 35 U.S.C. §§ 103 and 112.

COUNTERCLAIM COUNT VIII

(Declaratory Judgment Of Invalidity — '162 Patent)

98. The Lupin Counter-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of their Counterclaims.

99. One or more of the claims of the '162 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq*. By way of example and not of limitation, one or more of the claims of the '162 patent are invalid under 35 U.S.C. §§ 103 and 112.

PRAYER FOR RELIEF

WHEREFORE, the Lupin Counter-Plaintiffs respectfully request the Court enter judgment against Plaintiffs to include:

(a) a declaration that the Lupin Counter-Plaintiffs' submission of ANDA No. 90-692 seeking FDA approval to market the 500 mg and 1000 mg metformin hydrochloride extended release tablets described therein and the Lupin Counter-Plaintiffs' commercial manufacture, use, offer for sale, sale, or importation of the ANDA Products prior to the expiration of the '859 patent have not and will not infringe any claim of the '859 patent;

(b) a declaration that the Lupin Counter-Plaintiffs' submission of ANDA No. 90-692 seeking FDA approval to market the 500 mg and 1000 mg metformin hydrochloride extended release tablets described therein and the Lupin Counter-Plaintiffs' commercial manufacture, use, offer for sale, sale, or importation of the ANDA Products prior to the expiration of the '866 patent have not and will not infringe any claim of the '866 patent;

(c) a declaration that the Lupin Counter-Plaintiffs' submission of ANDA No. 90-692 seeking FDA approval to market the 500 mg and 1000 mg metformin hydrochloride extended release tablets described therein prior to the expiration of the '459 patent has not infringed any claim of the '459 patent;

(d) a declaration that the Lupin Counter-Plaintiffs' submission of ANDA No. 90-692 seeking FDA approval to market the 500 mg and 1000 mg metformin hydrochloride extended release tablets described therein prior to the expiration of the '162 patent has not infringed any claim of the '162 patent;

(e) a declaration that the claims of the '866 patent are invalid;

(f) a declaration that the claims of the '459 patent are invalid;

(g) a declaration that the claims of the '859 patent are invalid;

(h) a declaration that the claims of the '162 patent are invalid;

(i) a declaration that Plaintiffs are entitled to no damages, interest, costs, or other relief from or against the Lupin Counter-Plaintiffs for infringement of the '859 patent pursuant to 35 U.S.C. § 271(e)(4)(C) or any other provision or law;

(j) a declaration that Plaintiffs are entitled to no damages, interest, costs, or other relief from or against the Lupin Counter-Plaintiffs for infringement of the '866 patent pursuant to 35 U.S.C. § 271(e)(4)(C) or any other provision or law;

(k) a declaration that Plaintiffs are entitled to no damages, interest, costs, or other relief from or against the Lupin Counter-Plaintiffs for infringement of the '859 patent pursuant to 35 U.S.C. § 283 through 285 or any other provision of law;

(l) a declaration that Plaintiffs are entitled to no damages, interest, costs, or other relief from or against the Lupin Counter-Plaintiffs for infringement of the '866 patent pursuant to 35 U.S.C. § 283 through 285 or any other provision of law;

(m) adjudging that this case is exceptional pursuant to 35 U.S.C. 285, and awarding the Lupin Counter-Plaintiffs their reasonable attorneys' fees, expenses, and costs incurred in this action; and

(n) granting the Lupin Counter-Plaintiffs all such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Lupin Pharma and Lupin Ltd. demand a trial by jury on all claims so triable.

February 13, 2012

BAYARD P.A.

/s/ Stephen B. Brauerman (sb4952)

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